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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,431	12/19/2005	Hiromu Ohnogi	1422-0704PUS1	6348
2292 7590 04/16/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER CHEN, CATHERYNE	
			ART UNIT	PAPER NUMBER
			1655	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/16/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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mailroom@bskb.com

Office Action Summary

Application No.

10/561,431

Applicant(s)

OHNOGI ET AL.

Examiner

Catheryne Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/20/06, 12/19/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Currently, Claims 1-13 are pending. Claims 1-13 are examined on the merits.

Specification

The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating, does not reasonably provide enablement for preventing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prevent the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent a disease accompanying an abnormality in an amount of insulin or insulin response and

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or diabetic complications. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent a disease accompanying an abnormality in an amount of insulin or insulin response and or diabetic complications for all potential causes of disease accompanying an abnormality in an amount of insulin or insulin response and or diabetic complications. In addition, the art teaches disease accompanying an abnormality in an amount of insulin or insulin response and or diabetic complications prevention is not accepted as possible because many risk factors such as family history cannot be controlled (see http://www.medicinenet.com/insulin_resistance/article.htm). Because applicant's specification does not show prevention of a disease accompanying an abnormality in an amount of insulin or insulin response and or diabetic complications and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of disease accompanying an abnormality in an amount of insulin or insulin response and or diabetic complications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by

Hagiwara et al. (US 5338838).

Hagikawa et al. teaches Angelica keiskei extract with aqueous ethanol solution having a water content of 0 to 80% (column 1, line 60; column 2, lines 26-32) and 60% methanol (column 9, line 35).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Park et al. (Phytother. Res., 2002, Effects of Extract from Angelica Keiskei and its Component, Cynaroside, on the Hepatic Bromobenzene-metabolizing Enzyme System in Rats, 16: S24-S27).

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Claims 1-3, 7-13 are product-by-process claims. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In *re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972) ; In *re Fessmann*, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

The reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are from the same plant and are extracted in a similar manner, such as extracting with a water-containing alcohol. Alcohol itself contains water because of the property of alcohol. Different concentrations of alcohol can be achieved by diluting alcohol with water. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially

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in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Phytother. Res., 2002, Effects of Extract from Angelica Keiskei and its Component, Cynaroside, on the Hepatic Bromobenzene-metabolizing Enzyme System in Rats, 16: S24-S27).

Park et al. teaches air-dried aerial parts of *A. keiskei* extracted with methanol (Materials and Methods) and used as a health food and disease treatment (Results and Discussion). However, it does not teach the 40 (v/v)% or more and less than 100(v/v)%.

The reference also does not specifically teach adding the ethanol in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Phytother. Res., 2002, Effects of Extract from Angelica Keiskei and its Component, Cynaroside, on the Hepatic Bromobenzene-metabolizing Enzyme System in Rats, 16: S24-S27) as applied to claims 1-13 above, and further in view of Hagiwara (US 6022573).

Park et al. teaches air-dried aerial parts of *A. keiskei* extracted with methanol (Materials and Methods) and used as a health food and disease treatment (Results and Discussion). However, it does not teach the 40 (v/v)% or more and less than 100(v/v)%.

Hagiwara teaches *Angelica keiskei* (column 1, line 65) extracted in polar organic solvents, including alcohols such as ethanol (column 4, lines 11-13), for use in food products and drinks (column 5, lines 15-20).

The reference also does not specifically teach formulating the composition in the forms claimed by applicant and using ethanol. These pharmaceutical forms are well known in the art to be acceptable means of extracting a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant. Ethanol is a well known polar organic solvent. Thus, a person of ordinary skill in the art would reasonably expect that ethanol could be used in the

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composition of the reference. Such reasonable expectation would provide motivation to use ethnaol.

The references also do not specifically teach adding the ethanol in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S Hoffman
3-6-07

SUSAN COE HOFFMAN
PRIMARY EXAMINER

Catheryne Chen
Patent Examiner
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